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PATENT APPLICATION

LARYNGEAL AIRWAY DEVICE

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LARYNGEAL AIRWAY DEVICE

BACKGROUND OF THE INVENTION

[0001] The present invention relates to laryngeal airway devices. More specifically, the present invention relates to improved geometric and design configurations for laryngeal airway devices.

[0002] It is common practice to use an airway device known as a laryngeal mask for the administration of anesthetic and ventilation gases to a patient. These airways comprise a tube with an inflatable mask or cuff at one end, the tube being inserted in the patient's mouth so that one end is located in the hypopharynx and so that the mask forms a seal in this region with the surrounding tissue. Laryngeal masks are provided by many suppliers.

[0003] The laryngeal airway is a device that fills the gap between tracheal intubation and the use of a face mask. The laryngeal airway device is inserted blindly into the pharynx and forms a low pressure seal around the laryngeal inlet. It is minimally stimulating to the airway, thus avoiding the unwanted sympathetic stimulation associated with laryngoscopy. The laryngeal airway device provides a way of establishing an airway during anesthesia in both adults and children, and plays a useful role in management of the difficult airway.

[0004] As show in Fig. 1, a common laryngeal airway device is constructed of medical-grade silicone rubber with no latex in any part. This allows the laryngeal airway device to withstand repeated autoclaving. The device has a shaft or airway tube 1 ranging from 5.25 to 12 mm in internal diameter, depending on the size of the laryngeal airway device. The shaft is fused at an angle to a distal elliptical spoon-shaped mask 2 with an inflatable rim or cuff resembling a miniature face mask. The shaft opens into the concavity of the ellipse via an aperture having aperture bars 3 across the opening to prevent the epiglottis from falling back and blocking the lumen. Various different size laryngeal airway devices are available to accommodate different size patients, from neonates to adult patients.

[0005] When correctly positioned, the tip of the laryngeal airway device cuff lies at the base of the hypopharynx against the upper esophageal sphincter, the sides lie in the pyriform fossae, and the upper border of the mask lies at the base of the tongue, pushing it forward. The epiglottis often lies within the bowl of the laryngeal airway device, but the device functions satisfactorily with the epiglottis in the upright horizontal or downfolded

position. When the cuff is around the opening to the larynx, a syringe connects to the valve 4 to inject air into the cuff via the inflation line 5 to inflate the cuff, such that no gap is present between the cuff and the larynx. The inflation line 5 meets the cuff 2 at an inflation line inlet 8, which inlet 8 is typically also the mold extraction point or orifice used during the forming of the cuff 2. An inflation line balloon 6 reflects the degree of inflation of the cuff. Typically, the airway tube includes a securely attached 15 mm connector 7 at its proximal end.

[0006] However existing laryngeal airway devices suffer from various shortcomings. For example, the aperture bars across the airway opening prevent the entry of other devices, such as bronchoscopes and/or endotracheal tubes into the airway passage. The spoon-shaped cuff is inflated at its proximal end by a separate inflation line. In some devices, the inflation line inlet at the proximal end of the cuff is also the same as the mold extraction orifice used to form the cuff, and protrudes away from the surface of the cuff, resulting in a nonsmooth external surface for the cuff. The separate inflation line needs to be carefully handled as the laryngeal airway device is inserted into a patient's airway. It has been reported by many that the cuff folds back on itself as the laryngeal airway device is being inserted. The folded cuff prevents the cuff from being properly inflated thus preventing effective placement of the device. In addition, the commonly placed 15 mm connector at the proximal end of the airway tube can also prevent the insertion of other devices into the airway tube.

[0007] There is therefore a need for an improved laryngeal airway device that does not suffer from these shortcomings.

BRIEF SUMMARY OF THE INVENTION

[0008] The present invention is directed to a laryngeal airway device. In one embodiment, the present invention provides a laryngeal airway device having an airway tube which has an internal passage in the airway tube wall for receiving a cuff inflation line. The device also has a dome having an inlet and an outlet, which is connected at its inlet with the distal end of the airway tube; an annular spoon-shaped inflatable cuff connected with the periphery of the outlet of the dome; a cuff inflation line configured to be in fluid communication with the internal space of the cuff; and a multi-lobed aperture formed in the dome. The aperture is configured to be in fluid communication with the proximal end of the airway tube. The dome also has several protrusions forming the multi-lobed aperture, such that a flap is configured to prevent the obstruction of the aperture by a patient's epiglottis when the device is inserted into the patient.

[0009] In one aspect, the device also includes a protruding dome tip connected with the distal end of the outlet of the dome. The protruding dome tip's distal end is located in and in fluid communication with the internal space of the cuff.

[0010] In another aspect, the dome also includes a groove that is configured to hold the cuff inflation line in the dome.

[0011] In another aspect, the outlet of the dome further includes a tray portion, and the cuff further includes a channel on the inner surface of the annular shaped cuff, such that the channel is connected with the periphery of the outlet of the dome at the tray portion.

[0012] In another aspect, the cuff's outer surface is formed in the absence of external protrusions. The cuff also includes a mold extraction orifice at its distal end, which is formed on an internal surface of the cuff, and wherein the cuff inflation line is configured to be in fluid communication with the internal space of the cuff at an opening which includes the mold extraction orifice.

[0013] In another aspect, the device also includes a removable connector connected with the proximal end of the airway tube.

[0014] In another aspect, the cuff inflation line is configured to be in fluid communication with the internal space of the cuff at a distal end of the cuff. The device also includes an inflation line insertion point offset distally from the proximal end of the airway tube, where the insertion point serves as the proximal end and is integral with the internal passage.

[0015] For a further understanding of the nature and advantages of the invention, reference should be made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Fig. 1 is a diagram of a prior art laryngeal airway device.

[0017] Fig. 2 is a perspective view diagram of a laryngeal airway device in accordance with an embodiment of the present invention.

[0018] Fig. 3 is a detailed view diagram of the bottom or airway side of the distal end of the device of Fig. 2.

[0019] Fig. 4 is a detailed view diagram of Fig. 3 shown without the cuff.

[0020] Fig. 5 is another perspective view of the device of Fig. 4.

[0021] Fig. 6 is a top view diagram of the device of Fig. 3.

[0022] Fig. 7 is a detailed cross sectional view diagram of the distal end of a laryngeal airway device in accordance with an embodiment of the present invention.

[0023] Fig. 8 is a detailed view diagram of the cuff of a laryngeal airway device in accordance with an embodiment of the present invention.

[0024] Fig. 9 is a diagram of an embodiment of the airway tube of the laryngeal airway device in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0025] Fig. 2 is a perspective view diagram of a laryngeal airway device 10 in accordance with an embodiment of the present invention. An airway tube 100 connects at the tube's distal end with a dome 300. At its proximal end the tube 100 is connected with a removable connector 104. In contrast to the more common way of adhesively attaching the connector with the tube, the connector 104 is press fitted into place and not adhesively adhered with the tube 100. In this manner, the connector 104 is easily removable to allow the insertion of another device, such as for example an endotracheal tube or bronchoscope through the airway tube 100. An endotracheal intubation introduces a tube into the trachea to provide an open airway to administer oxygen, gaseous medication, or anesthetics; it may also be done to remove blockages, or to view the interior walls. Therefore, by enabling the removal of the connector 104, the in-place laryngeal airway device can also facilitate an endotracheal intubation. A cuff 200 connects with the dome 300. The dome 300 has a multi-lobe shaped aperture and is described in further detail below. An inflation line 400 enters the tube 100 at the inflation line insertion location 407 and feeds through the tube 100. The inflation line 400 continues through the tube 100, runs through a groove in the dome 300, and connects with the cuff at the distal end of the cuff. The cuff 200 has a smooth external surface that is void of any protrusions. A syringe is used to connect with the valve 404 to fill the cuff with air to inflate it. The valve 404 is a check valve and prevents the passive backflow of air from the cuff. An inflation balloon 402 connected downstream of the valve 404 provides an indication of the inflation level of the cuff. The inflation line insertion location 407 is offset back from the proximal end of the tube 100 to enable the operation of the device even when there is a need to cut off the proximal end. The offset of the inflation line insertion location 407 from the proximal end of the tube 100 allows for a significant portion of the tube 100 to be cut off and still not adversely impact the inflation or deflation operation of the cuff.

[0026] Fig. 3 is a detailed view diagram of the bottom or airway side of the distal end of the device of Fig. 2. Fig. 3 shows the tube 100 ending at the dome 300. The dome has an aperture or opening 302 and a groove along its upper portion. The groove is configured to receive the inflation line 400. The inflation line 400 travels along the groove and meets connector 406, which is used to deliver air to inflate the cuff 200. The aperture has multiple lobes, preferably elongated. Defining the lobes are protrusions which separate them. One of the protrusions is formed at the proximal end. This protrusion comprises a flexible flap, preferably tongue-shaped, and larger than the other protrusions. The smaller protrusions are preferably less flexible, or more rigid than the flap. The aperture 302 is shaped in this manner to help prevent the epiglottis's obstruction of the airway. In addition, the protrusions of the multi-lobed design (as opposed to the more common bars that fully extend across such an opening) allow the entry of other devices, (*e.g.*, a bronchoscope or an endotracheal tube) into the airway passage. When such other devices are being entered into the airway passage, the flap bends and pushes the epiglottis back enabling the effective insertion of the bronchoscope or other device into the airway. None of the protrusions extend fully across the airway opening. The protrusions may be integrally molded with the dome.

[0027] The cuff 200 is attached with the dome using known techniques. In addition, the cuff includes a channel 202 on its inner surface that is configured to couple with a complimentarily shaped tray 412 (shown in Fig. 4) on the lower side of the dome. The channel 202 and tray 412 together provide for an improved bonding surface that provides a more secure structure for adhering the cuff with the dome. The channel and tray arrangement also ensure a proper mechanical fit by enabling a centered fit between the spoon-shaped cuff and dome. The channel and tray arrangement also enable a more repeatable assembly of the cuff with the dome.

[0028] Fig. 4 is a detailed view diagram of Fig. 3 shown without the cuff 200. As set forth above, Fig 4 shows the tube 100 ending at the dome 300. Surrounding the dome, at least partially, is tray 412. The channel 202 (shown in Fig. 3) and tray 412 together provide an improved bonding surface that provides a more secure structure for adhering the cuff with the dome. The tray 412 may be integrally formed with the dome 300, or it may be a separate piece that is adhered to or bonded with the dome 300. The dome 300 has a multi-lobed aperture 302 and a groove along its upper portion. The groove is configured to receive the inflation line 400. The inflation line 400 meets connector 406, which is used to deliver air to inflate the cuff 200. The multi-lobed aperture 302 is shaped in this manner to help prevent the epiglottis's obstruction of the airway. Also shown is a protruding dome tip 408

connected with and extending from the connector 406. The protruding dome tip 408 fits inside the cuff at the cuff's distal end to help prevent the cuff from folding back during insertion. In one embodiment, the protruding dome tip 408 is less elastic than the cuff, to help prevent the cuff from folding back on itself when the device is being inserted into a patient. In one embodiment, the protruding dome tip 408 has a cross cut structure or side slits 410 at its distal end to help prevent possible air-occlusion, especially during the removal of the laryngeal airway device that could be caused by the adjacent placement of the cuff's interior wall against the distal end of the dome tip 408. Other slit or cut forms can be envisioned that enable the flow of air between the cuff and the air inflation line, even when the cuff's internal surface is held against the dome tip. Such cut forms include a slot, a Philips type slot, a star form and so on. Fig. 5 is another perspective view of the device of Fig. 4.

[0029] Fig. 6 is a top view diagram of the device of Fig. 3. Fig. 6 shows the tube 100 ending at its distal end at the dome 300. The dome 300 is encircled by the complimentarily and spoon-shaped cuff 200. The cuff 200 has a smooth external surface to help prevent trauma that could be caused by externally protruding projections from the cuff's external surface, in contrast to common prior art devices (*e.g.*, see Fig. 1). Mold extraction orifice 204 is located at the distal internal end (instead of proximal external end, *e.g.*, as shown in Fig. 1) of the cuff 200 and is at the same location as that of the dome insertion to ensure a smooth external cuff surface. Moreover, having the mold extraction orifice 204 located at the same location as that of the dome insertion, ensures a simplified manufacturing process for the laryngeal airway device in accordance with the embodiments of the present invention, and thus will increase production throughput and reduce the cost of each unit.

[0030] Fig. 7 is a detailed cross sectional view diagram of the distal end of a laryngeal airway device in accordance with an embodiment of the present invention. Fig. 7 shows the tube 100 connected at its distal end with the dome 300. The tube has a passage 102 formed therein to receive the air inflation line 400. The air inflation line passes through passage 102 in the tube 100, continues in groove 302 in the dome 300 and ends at the protruding dome tip 408. Dome tip 408 fits inside the cuff 200 to provide a flow passage for inflating or deflating the cuff.

[0031] Fig. 8 is a detailed view diagram of the cuff 200 of a laryngeal airway device in accordance with an embodiment of the present invention. The cuff 200 includes a channel 202 on its inner surface that is configured to couple with a complimentarily shaped

tray 412 (shown in Fig. 4) on the lower side of the dome 300. The cuff 200 is formed without any protrusions on the external surface of the cuff, as described above.

[0032] Fig. 9 is a diagram of an embodiment of the airway tube 100 of the laryngeal airway device in accordance with an embodiment of the present invention. Fig. 9 shows the airway tube 100 to include a passage 102 that is configured to receive the air inflation line 400 (shown in Fig. 2). Furthermore, Fig. 9 shows the inflation line insertion location 407 formed offset from the proximal end of the tube 100. An inflation line 400 (shown in Fig. 2) enters the tube 100 at the inflation line insertion location 407 and feeds through the tube 100 to connect with and inflate or deflate the cuff.

[0033] The improved device described herein is manufactured using medical grade plastic materials, such as for example a medical grade PVC. The novel features of the improved device described herein can all be combined into one laryngeal airway device, or alternately a suite of different laryngeal airway devices can be produced each having one or a combination of the novel features that have been described herein. It is also envisioned that various different size devices according to the embodiments of the present invention will be made available to accommodate different size patients, from neonates to adult patients.

[0034] As will be understood by those skilled in the art, the present invention may be embodied in other specific forms without departing from the essential characteristics thereof. For example, a device in accordance with the embodiments of the present invention can be made using various different materials and in many different sizes. These other embodiments are intended to be included within the scope of the present invention, which is set forth in the following claims.